1 Summary of safety and effectiveness

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Date Summary Prepared: April 17th 2014

Device Identification

A.	Generic Device Name:	System, optical position/movement recording
B.	Trade/Proprietary Name:	SMART-D
C.	Classification:	Unclassified
D.	Product Code:	LXJ

Device description

SMART-D is a motion capture and analysis system. It is based on optoelectronic technology and uses passive reflective markers, infrared cameras and strobes.

SMART-D executes the three-dimensional reconstruction of trajectories of a certain number of small reflective markers on the body to be analyzed.

Using a set of cameras placed all around the volume where the action is performed, the system acquires the movement of the subject; cameras position is computed after a calibration step.

Intended Use

SMART-D is a system for motion analysis, intended for the recording and analysis of human movement patterns in the fields of rehabilitation, sports medicine, ergonomics.

Substantial equivalents

The SMART-D device is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	510(K) Holder	510(k) No.	Date Cleared
PEAK MOTUS	PEAK PERFORMANCE TECHNOLOGIES, INC	K030714	16 May 2003
CODA CX1 MOTION ANALYSIS SYSTEM	CHARNWOOD DYNAMICS LTD.	K033514	6 Jan 2004

In further support of a substantial equivalence determination, Section 12 provides a comparison chart of SMART-D and the predicate devices.

Technological characteristics

A comparison of the technological characteristics of SMART-D and the predicate devices has been performed. The results of this comparison demonstrate that the system for motion analysis SMART-D is equivalent to the marketed predicate devices.

The two tables below show the comparison of technical characteristics of SMART-D system compared to the characteristics of predicate devices:

- Table 1 contains the summary of the technical characteristics which are the same for both devices;
- Table 2 contains the summary of the different technical characteristics and provides an explanation of how they are comparable to the predicate device.

Table 1 - Same Technical Characteristics

Characteristics	SMART-D System	PEAK MOTUS	CODA CX1 MOTION ANALYSIS SYSTEM
CFR Section	Unclassified	Unclassified	Unclassified
Pro-code	LXJ	LXJ	LXJ
Classification name	System, optical position/movement recording	System, optical position/movement recording	System, optical position/movement recording
Intended / Indications For Use	SMART-D is a system for motion analysis, intended for the recording and analysis of human movement patterns in the fields of rehabilitation, sports medicine, ergonomics.	Computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in gait analysis, prosthetic design, pre/post rehabilitation evaluation, physical therapy, and the like.	The Coda CX I Motion Analysis System has general application to measurement and recording of 3D position and movement, including human movement. It is appropriate for use in assessment of the 3D motion of the limbs and body of patients who have some impairment

			of movement functions of either a neurological or orthopaedic cause.
System Components	Workstation + Cameras + Software	Workstation + Cameras + Software	Workstation + Cameras + Software
Software tools	SMARTcapture, SMARTtracker, SMARTanalyzer, SMARTclinic to achieve: **a)** Real-time visualization of signals of all integrated devices **b)** 3D kinematics reconstruction Validated by international scientific community protocols **c)** Tool for easy construction of analysis protocols **d)** Multimedia customizable and web reporting	Vicon Motus **a)** Advanced video or 3D-optical-motion-capture module **b)** 2D and/or 3D kinematic calculation and display software Analog acquisition module **c)** 3D pan and tilt module KineCalc mathematical analysis module **d)** Peak Motus Gait Analysis Template	**a)** Realtime displays to verify marker location Fully labelled data appears immediately after acquisition from Codamotion active marker system **b)** Switch between different projects in seconds Options for simultaneous EMG and Force Vector Overlay Full standardised gait analysis package available **c)** Graphs and stick figure displays Highly configurable analysis setups
Contraindications	Not needed	Not needed	Not needed
Target population	All population	All population	All population
Electrical Safety	AAMI/ANSI ES60601-1:2005 and further amendments	SAME	SAME
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Power Supply	110 V, 60 Hz	110 V, 60 Hz	110 V, 60 Hz
Frame rate	200 fps	VCam/SV Cam 200 fps	Not available
Acquisition Frequencies	250 Hz (up to 500 Hz)	up to 250 Hz progressive up to 500 Hz progressive up to 1000 Hz progressive	Sampling Rates vs. Marker Numbers 100Hz for 56 markers 400Hz for 12 markers
Light emission	Infrared	Infrared	Not available

Table 2 - Different Technical Characteristics			
Characteristics	**SMART-D System**	**PEAK MOTUS**	**CODA CX1 MOTION ANALYSIS SYSTEM**
Max Input power	950 W	15-20 W for single unit	Not available
The Max Input power does not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices.			
Number of cameras	Up to 16 digital TVC	up to 12 cameras on one PC	Up to 16 digital inputs
The different number of cameras is comparable through the devices as it doesn't bring a technological difference, as the difference consists of a higher number of digital inputs from which the trajectory is reconstructed that is higher in SMART-D System and CODA CX1 MOTION ANALYSIS SYSTEM, with 16 cameras, than PEAK MOTUS with 12 cameras.			
Resolution (pixel)	800 H x 600 V	MCam-2 59.94: 1272 H x 1024 V MCam-2 100: 1266 H x 1024 V MCam-2 119.88: 1266 H x 940 V MCam-2 250: 816 H x 656 V MCam-2 500: 498 H x 480 V MCam-2 1000: 498 H x 210 V VCam/SV Cam : 648 H x 493 V MCam (PAL): 1011 H x 1024 V 1000 H x 972 V MCam (NTSC): 1012 H x 987 V 947 H x 881 V All Vicon MX cameras are built for speed at their full frame resolutions - 370fps for the 4 Megapixel F40, 240fps for the MX-3+ and a massive 500fps for the 2 Megapixel F20. On top of this all the cameras can be	$1/10^{th}$ of pixel in a 50 Megapixel camera

		run at speeds up to 2000fps at reduced, windowed resolutions for particularly high speed applications	
The Resolution (pixels) does not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *The only effect that this characteristic produces is a better or worse capability to detect the markers in the space and displaying them on the video.*			
Acquisition Frequencies	250 Hz (up to 500 Hz)	up to 120Hz progressive up to 250 Hz progressive up to 500 Hz progressive up to 1000 Hz progressive	Sampling Rates vs. Marker Numbers 100Hz for 56 markers 200Hz for 28 markers 400Hz for 12 markers 800 Hz for 6 markers
The Acquisition frequency does not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *The only effect that this characteristic produces is a different quantity of data in the time (frames in the time) to reconstruct the trajectory of the markers in the space.*			
Weight	20 Kg	2.5 kg	5 kg
The weight of workstation does not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *The three devices are not portable, so the weight does not influence their use and application.*			
Dimensions	450mm long x 330mm high x 500 mm deep	443.4 mm long x 43.6mm high x 348.2mm deep	800mm long x 112mm high x 81mm deep
The Dimensions of workstation do not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *The three devices are not portable, so the dimensions do not influence their use and application. Moreover the difference of dimensions between the three workstations is negligible respect to the environment in which they have to be placed.*			
Sensor Technical Characteristics	**Wave length:**	880 nm	Not available	Not available
	Output angle	40°	Not available	Not available
	Modulation	Square wave synchronized with the acquisition frequency, Duty Cycle 0÷0.5 ms	Not available	Not available
Lens		C-mount compatible (std. 8 mm)	Not available	Not available

The Lenses and Sensor technical characteristics do not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as they do not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *The difference brought by those differences is in the quality of the image provided to the system.*			
Options	None	SAME	Tripod Mount for cx1 units Gait Wand Set Wired Strobe Adapter unit and Drive Box Extension Cable External Strobe Panel for Active Hub or Mini Hub
The options do not bring a point of non-substantial equivalence between the SMART-D System and the predicate devices, as they do not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices. *Options are optional configurations or accessories to the main system which are not needed for its normal functioning and do not influence it.*			

Performance Data

The performance data indicate that the system for motion analysis SMART-D meets all specified requirements, and is substantially equivalent to the predicate device.

Conclusions

The non-clinical tests performed on the SMART-D System provided in Appendix 4, demonstrate that the SMART-D System is as effective and performs as the predicate devices. The acceptance criteria for each test item included the appropriate device specification or expected operation results. All acceptance criteria were met in the testing and the overall performance bench testing concluded that the SMART-D system had passed all the performance requirements defined by the System Requirement Specifications (provided in Appendix 2). The effectiveness and performance of the system are tested through the subtest: SMART capture, SMART tracker, SMART analyser, SMART clinic, which verify the same functionalities of the predicate devices as described in the comparison below:

Functionality	**SMART-D System**	**PEAK MOTUS**	**CODA CX1 MOTION ANALYSIS SYSTEM**
Calibration and Signals acquisition	SMARTcapture: **a)** Real-time visualization of signals of all integrated devices	Vicon Motus **a)** Advanced video or 3D-optical-motion-capture module Analog acquisition module	**a)** Realtime displays to verify marker location Fully labelled data appears immediately after acquisition from Codamotion active marker system
Trajectory reconstruction, signal	SMARTtracker: **b)** 3D	**b)** 2D and/or 3D	**b)** Switch between

elaboration	kinematics reconstruction Validated by international scientific community protocols	kinematic calculation and display software	different projects in seconds Options for simultaneous EMG and Force Vector Overlay Full standardised gait analysis package available
Management of acquired data, customizable analysis protocols	SMARTanalyzer: **c)** Tool for easy construction of analysis protocols	**c)** 3D pan and tilt module KineCalc mathematical analysis module	**c)** Graphs and stick figure displays Highly configurable analysis setups
Report drafting, data visualization	SMARTclinic: **d)** Multimedia customizable and web reporting	**d)** Peak Motus Gait Analysis Template	

The EMC and Electrical Safety Tests performed on the SMART-D System and the predicate devices are the same and demonstrate that the SMART-D System complies with the AAMI/ANSI ES60601-1:2005 and further amendments and IEC 60601-1-2, and that it is as safe, as effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

BTS Spa
c/o Enrico Bisson
ISO plan
Via Della Croce Rossa, 11
Padova, Italy, 35129

Re: K131660
Trade/Device Name: SMART-D
Regulatory Class: Unclassified
Product Code: LXJ
Dated: March 12, 2014
Received: March 18, 2014

Dear Mr. Bisson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K131660

Device Name

SMART-D

Indications for Use *(Describe)*

SMART-D is a system for motion analysis, intended for the recording and analysis of human movement patterns in the fields of rehabilitation, sports medicine, ergonomics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.17 13:35:53 -04'00'

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